

RECEIVED
CENTRAL FAX CENTER

OCT 31 2006

Appl. No. 10/643,681
Docket No.: 254/057CON
Page 10REMARKS

Claims 24-30 and 38-59 are pending in this application. Claims 24-30 and 38-59 were rejected under the judicially created doctrine of obviousness-type double patenting. Claims 25-30 and 41-59 were rejected under 35 U.S.C. §112, second paragraph. Claims 24 and 38-40 were rejected under 35 U.S.C. §102(b).

By this amendment, claims 25-30 and 56 have been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendment can be found, *inter alia*, throughout the specification and the claims as originally filed.

The amendment is made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and cancelled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein, thereby placing this case into condition for allowance.

Rejections under Obviousness-type Double Patenting

Claims 24-30 and 38-59 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-35 of U.S. Pat. No. 6,114,304. Claims 24-30, 38, 40-57, and 59 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-18 of U.S. Pat. No. 6,417,164. Submitted herewith are terminal disclaimers for the present application and U.S. Pat. Nos. 6,114,304 and 6,417,164. Accordingly, Applicants respectfully request that the rejections based on the claims of these patents be withdrawn.

Appl. No. 10/643,681
Docket No.: 254/057CON
Page 11

Rejections under 35 U.S.C. §112, second paragraph

Claims 25-30 and 41-59 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

Although Applicants believe that the claims were sufficiently definite when considered in view of the specification and the understanding of those of skill in the art, Applicants have attempted to respond to the concerns of the Examiner in order to enhance clarity and to facilitate disposition of the present case.

In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §112, second paragraph.

Rejections under 35 U.S.C. §102

Claims 24 and 38-40 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Pat. No. 4,451,394 (hereinafter "the '394 patent"). Applicants respectfully traverse this rejection.

The '394 patent describes dodecapeptides of a particular formula and use of the same in treating patients with diabetes mellitus and excessive growth hormone secretion. The Examiner characterizes the present invention as being directed to administration of "an amylin or an amylin agonist" and asserts that the dodecapeptide of the '394 patent "reads on an amylin agonist analogue according to the definition recited in the instant specification." Office Action, pages 7-8. Applicants respectfully disagree with this characterization of the claimed invention and with this assertion regarding the teaching of the '394 patent.

The claimed invention is directed to a method of reducing or moderating a postprandial rise in plasma glucose in a mammal comprising administering an amylin or an amylin agonist analogue to the mammal, where the amylin agonist analogue is a peptide. As described in the specification, the "term "amylin agonist analogue" is understood to refer to derivatives of an amylin which act as amylin agonists." Original specification, page 22, lines 6-8; substitute specification, page 13, lines 15-16. Thus, the term "amylin agonist analogue" describes the

Appl. No. 10/643,681
Docket No.: 254/057CON
Page 12

peptide both structurally and functionally. The amylin agonist analogue is structurally a derivative of an amylin and functionally an amylin agonist.

As noted by the Examiner, the term "amylin agonist" "refers to compounds which mimic the effects of amylin" and, thus, "amylin itself and amylin agonist analogues may also be referred to broadly as amylin agonist." Original specification, page 22, lines 3-6; substitute specification, page 13, lines 12-15. Although amylin agonist analogues have amylin agonist activity, not all compounds with amylin agonist activity are necessarily analogues of amylin. Even if one were to assert that dodecapeptides of the '394 patent have amylin agonist activity, which Applicants decidedly do not, the dodecapeptides of the '394 patent are certainly not amylin analogues. Thus, the '394 patent does not describe amylin agonist analogues and does not teach the claimed invention.

Thus, Applicants respectfully submit that the cited reference does not anticipate the claimed invention.

Accordingly, Applicants respectfully request reconsideration ad withdrawal of the rejection under 35 U.S.C. §102(b).

Appl. No. 10/643,681
Docket No.: 254/057CON
Page 13

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims is respectfully requested. If the Examiner feels that a telephone interview would serve to facilitate resolution of any outstanding issues, the examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if a fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 254/057CON. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Date: 31 October 2006

Respectfully submitted,

AMYLIN PHARMACEUTICALS, INC.

Karen R. Zachow
Karen R. Zachow, Ph.D.
Reg. No. 46,332

Amylin Pharmaceuticals, Inc.
9360 Towne Centre Drive
San Diego, California 92121
Phone (858) 552-2200
Facsimile (858) 552-1936